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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,398	02/27/2004	Kathleen M. Miller	98-P0151US2	4925

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EXAMINER	
SWEET, THOMAS	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/789,398	MILLER ET AL.	
	Examiner	Art Unit	
	THOMAS J. SWEET	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-104* is/are pending in the application.

4a) Of the above claim(s) *1-72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *73-104* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/6/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 07/06/2010 have been fully considered but they are not persuasive. Regarding the 102, Solomon et al discloses Chlorohexdine extruded in a homogeneous polymer which meets the current and previous claim. Applicant does disclose Chlorohexdine as one of the antimicrobial agents which inherently is a microbial attachment/biofilm synthesis inhibitor (i.e. microbes can attach or form films, if they are dead). Applicant fail to establish as a matter of fact that Chlorhexidine isn't a microbial attachment/biofilm synthesis inhibitor. Applicant wrongly suggests that the claim 1 requires three components, since a single agent can be both an antimicrobial agent and a microbial attachment/biofilm synthesis inhibitor. Regarding the 103, Modak et al comments do not rise to the level of destroying the reference since the resulting device is substantially the same, Solomon et al establishes the equivalents in the art of urethral stents to dipping, problematic is not an exclusion and it is unclear that anything other than coating is problematic (i.e. the medical device isn't being treated with polymer, it is the polymer and clearly doesn't require a polymer coating). Functional substitution is one of the most basic exemplary rationales.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 73-74, 84, 95, 97 and 103 are rejected under 35 U.S.C. 102(a) as being anticipated by Solomon et al. (6261271). Solomon et al discloses a stent comprising

(a) a polymeric tubular shaft having more than one layer (e.g. fig. 7, col 6 lines 15-22), said polymeric tubular shaft comprising a first annular layer (22) comprising an extruded homogenous mixture of a matrix polymer (abs), an antimicrobial agent and a microbial attachment/biofilm synthesis inhibitor (Chlorhexidine, one of the same materials currently disclosed for this purpose) that form a single distinct matrix polymer region;

(b) a first polymeric barrier layer at least partially covering an interior surface of said first annular layer (the inner of the tri-layer, col 6 lines 15-22); and

(c) a second polymer barrier layer at least partially covering an exterior surface of said first annular layer (the outer of the tri-layer, col 6 lines 15-22).

Regarding 74, stent is a ureteral stent (col 4 lines 1-7).

Regarding 95 and 97, Chlorhexidine is anti-inflammatory.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 73-75, 80-90, 94-99 and 103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Modak et al (US 6224579 from the IDS) in view of Solomon et al. (6261271).

Modak et al discloses a ureteral stent (col 4, lines 16-36) comprising a polymeric tubular shaft having more than one layer (i.e. coating), said polymeric tubular shaft comprising a first annular layer comprising matrix polymer comprising, an antimicrobial agent (triclosan, title),and a microbial attachment/biofilm synthesis inhibitor (Ag EDTA, col 4, lines 3-14) a first polymeric barrier layer at least partially covering an interior surface of said first annular layer and a second polymer barrier layer at least partially covering an exterior surface of said first annular layer (i.e. a dip coated stent has a layer inside and out). However, Modak et al remain silent as to using extrusion to prepare the tubing and agent resulting in a homogeneous bulk distribution. Solomon et al. discloses another ureteral stent utilizing twin screw extrusion with a homogeneous melt for the purpose of distribution of the agent in the base polymer (abs, Solomon et al. also discloses the dip coating method as and equivalent). It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the extrusion method of Solomon et al in place of the dip coating method of Modak et al in order to distribution of the agent in the base polymer. Such a modification amounts to mere substitution of one agent distribution method for another within the are of implantable tubing (ureteral stents)

Regarding claim 75, see Modak et al col 4 line 45-.1-20% triclosan.

Regarding claims 80 and 89, lubricous surface see Modak et al col 15, lines 40-45.

Regarding claims 81, obviousness of use of plural apertures in the walls of a urethral stent is now admitted prior art.

Regarding claims 82, 83 and 88, obviousness of bismuth subcarbonate as a radio-opacifying agent in the art of ureteral stents is now admitted prior art.

Regarding claims 86 and 94, obviousness of end regions of different durometer valve in the art of ureteral stents is now admitted prior art.

Regarding claims 85 and 87, obviousness of wall thickness in the .2-.8 mm range in the art of ureteral stents is now admitted prior art.

Regarding claims 97-99, Modak et al discloses "a silver compound, "(Ag EDTA) "and an anti-inflammatory agent" (salicylic acid, col 10, lines 18-21).

Claims 76-79 and 91-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Modak et al in view of Solomon et al as applied to claims 73 and 87 and in further view of Schwarz et al (US 2001/0022988). Modak et al as modified discloses a stent as discussed above. However, Modak et al does not disclose use of ethylene vinyl acetate copolymer. Schwarz et al discloses another stent using ethylene vinyl acetate copolymer for the purpose of holding drugs for local delivery. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute ethylene vinyl acetate copolymer of Schwarz et al for the drug polymer of Modak et al in order to locally deliver drug. Such a modification amounts to mere substitution of one functionally equivalent drug polymer for another within the art of stents.

Regarding claims 78-79, It is a matter of mere design choice to vary the percentages of drug to polymer which is not patentably distinct from the prior art.

Regarding claims 91-93, the 5-20 wt % triclosan and EVA ureteral stent as rejected above is structurally identical and therefore would function the same as the claimed stent.

Claims 100-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Modak et al in view of in view of Solomon et al as applied to claims 73 and 95 and in further view of

Buscemi et al (US 5693034). Modak et al as modified discloses a stent as discussed above including use of suitable hydrophilic polymer as a lubricant (col 10, lines 14-17). However, Modak et al remain silent as to the suitable hydrophilic polymer being polyacrylic acid. Buscemi et al teaches another lubricant of hydrophilic polymer using polyacrylic acid for the purpose of lubricating medical devices. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the polyacrylic acid coating of Buscemi et al as the lubricous coating of Modak et al in order to lubricate the medical device. Such a modification amounts to mere substitution of one functionally equivalent lubrication coating for another within the art of medical devices.

Claims 102 and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Modak et al in view Solomon et al as applied to claims 73 and further in view of Falk et al. (US 6048844). Modak et al as modified discloses a stent as discussed above. However, Modak et al does not disclose the use of ketorolac as an anti-inflammatory. Falk et al. discloses another stent using ketorolac for the purpose of functioning as an anti-inflammatory. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute ketorolac as taught by Falk et al for the salicylic acid of Modak et al in order to function as an anti-inflammatory. Such a modification amounts to mere substitution of one functionally equivalent anti-inflammatory for another within the art of stents.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to THOMAS J. SWEET at telephone number (571)272-4761.

/Thomas J Sweet/
Supervisory Patent Examiner, Art Unit 3739